

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 08830-0385US1
INTERNATIONAL APPLICATION NO. PCT/GB2004/03342	INTERNATIONAL FILING DATE 30 July 2004 (20.07.2004)	U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/566,417
TITLE OF INVENTION IN VITRO GENE EXPRESSION ASSAY FOR DETERMINING FLUOROPYRIDIMINE SENSITIVITY IN CHEMOTHERAPY		PRIORITY DATE CLAIMED 30 July 2003 (30.07.2003)
APPLICANT(S) FOR DO/EO/US Patrick Gerard JOHNSTON; David Broderick LONGLEY; Pamela Joan MAXWELL		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
- ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
- ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
- ☐ The US has been elected (Article 31).
- ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - ☐ is attached hereto (required only if not communicated by the International Bureau).
 - ☐ has been communicated by the International Bureau.
 - ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
- ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - ☐ is attached hereto.
 - ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
- ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - ☐ are attached hereto (required only if not communicated by the International Bureau).
 - ☐ have been communicated by the International Bureau.
 - ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - ☐ have not been made and will not be made.
- ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
- ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
- ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

- ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
- ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
- ☐ A preliminary amendment.
- ☐ An Application Data Sheet under 37 CFR 1.76.
- ☐ A substitute specification.
- ☐ A power of attorney and/or change of address letter.
- ☒ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. (substitute)
- ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
- ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for

EXPRESS MAIL Mailing Label Number: Date of Deposit: January 31, 2007 I hereby certify that this correspondence, along with any paper referred to as being attached or enclosed, and/or fee, is being deposited with the United States Postal Service, "EXPRESS MAIL-POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10, on the date indicated above, and addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10 EV299886853US Signature of person mailing page: KAREN M. SPINA Type or print name of person
---	---

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/566,417		INTERNATIONAL APPLICATION NO. PCT/GB2004/03342		ATTORNEY'S DOCKET NUMBER 08830-0385US1	
20. Other items or information: Response to Notification to Comply with Requirements for Patent Applications Containing Nucleotide and/or Amino Acid Sequence Disclosures; copy of Notification (FORM PTO/DO/EO/922); Written (on paper) copy of substitute Sequence Listing; Statement to Support Submission in Accordance w/37 CFR 1.821-1.825; Postcard Receipt					
The following fees have been submitted				CALCULATIONS PTO USE ONLY	
21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300				\$	
22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c))				\$	
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 All other situations..... \$200				\$	
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400 All other situations..... \$500				\$	
TOTAL OF 21, 22 and 23 =					
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250	\$	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =		x \$ 50	\$	
Independent claims	- 3 =		x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
TOTAL OF ABOVE CALCULATIONS =				\$	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.					
SUBTOTAL =				\$	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
TOTAL NATIONAL FEE =				\$ - 0 -	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
TOTAL FEES ENCLOSED =				\$ - 0 -	
				Amount to be refunded:	\$
				Amount to be charged	\$

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

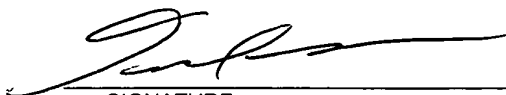
- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0573. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038. The PTO-2038 should only be mailed or faxed to the USPTO. However, when paying the basic national fee, the PTO-2038 may NOT be faxed to the USPTO.

ADVISORY: If filing by EFS-Web, do **NOT** attach the PTO-2038 form as a PDF along with your EFS-Web submission. Please be advised that this is **not** recommended and by doing so your **credit card information may be displayed via PAIR**. To protect your information, it is recommended paying fees online by using the electronic payment method.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

DANIEL A. MONACO, Esq.
Drinker Biddle & Reath LLP
One Logan Square
18th and Cherry Streets
Philadelphia, PA 19103-6996
TEL: (215) 988-3312
FAX: (215) 988-2757



SIGNATURE

DANIEL A. MONACO

NAME

30,480

REGISTRATION NUMBER

Customer No. 23973



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/566,417	Patrick Gerard Johnston	088300385US1

23973

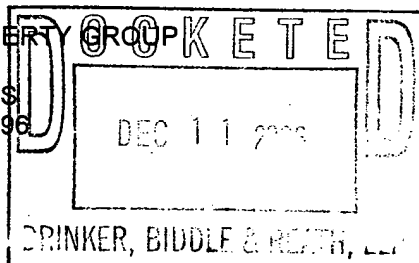
DRINKER BIDDLE & REATH

ATTN: INTELLECTUAL PROPERTY GROUP

ONE LOGAN SQUARE

18TH AND CHERRY STREETS

PHILADELPHIA, PA 19103-6996



INTERNATIONAL APPLICATION NO.

PCT/GB04/03342

I.A. FILING DATE

07/30/2004

PRIORITY DATE

07/30/2003

CONFIRMATION NO. 1909

371 FORMALITIES LETTER



OC000000021474995

Date Mailed: 12/05/2006

NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant is given **TWO MONTHS FROM THE DATE OF THIS NOTICE** within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patent Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patent Software Program Help @ ebc@uspto.gov

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.

<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

MAMIE P PERSON

Telephone: (703) 308-9140 EXT 227

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/566,417	PCT/GB04/03342	088300385US1

FORM PCT/DO/EO/922 (371 Formalities Notice)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
ACTING AS THE DESIGNATED/ELECTED OFFICE

In re: Patent application of: Patrick Gerard JOHNSTON
David Broderick LONGLEY
Pamela Joan MAXWELL

Application No: 10/566,417
(International Application No: PCT/GB2004/003342)

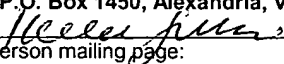
Filed: (International Application: 30 July 2004 (30.07.2004))

For: IN VITRO GENE EXPRESSION ASSAY FOR DETERMINING
FLUOROPYRIDIMINE SENSITIVITY IN CHEMOTHERAPY

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO NOTIFICATION TO COMPLY WITH REQUIREMENTS
FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE
AND/OR AMINO ACID SEQUENCE DISCLOSURES**

This response to the NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES is due on February 5, 2007 and is timely filed. No fee is believed due to support this submission. However, should any fee be due, please charge Deposit Account No. 50-0573.

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10	
EXPRESS MAIL Mailing Label Number:	EV299886853US
Date of Deposit:	January 31, 2007
I hereby certify that this correspondence, along with any paper referred to as being attached or enclosed, and/or fee, is being deposited with the United States Postal Service, "EXPRESS MAIL-POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10, on the date indicated above, and addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
	
Signature of person mailing page:	
KAREN M. SPINA	
Type or print name of person	

Amendments to the Specification:

Please replace the sequence listing presently on file in paper and computer-readable form with the substitute sequence listing submitted herewith in paper and computer readable form.

REMARKS

In response to the NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES, Applicant encloses herewith:

1. copy of the aforesaid Notification;
2. Diskette containing the substitute computer readable form of the sequence listing complying with the requirements of 37 CFR 1.822 and/or 1.823; and
3. Written (on paper) copy of the substitute sequence listing.

**STATEMENT TO SUPPORT SUBMISSION
IN ACCORDANCE WITH 37 C.F.R. §§1.821-1.825**

The sequence listing information recorded on the diskette containing the substitute computer readable form is identical to the written (on paper) copy of the substitute sequence listing submitted herewith, and includes no new matter.

Respectfully submitted,

PATRICK GERARD JOHNSTON *et al.*

BY 

DANIEL A. MONACO
Registration No. 30,480
DRINKER BIDDLE & REATH LLP
One Logan Square
18th and Cherry Streets
Philadelphia, PA 19103-6996
Tel.: (215) 988-3312
Fax: 215) 988-2757
Attorney for Applicants